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41. (New) A kit according to Claim 40, wherein the kit is biocompatible.

42. (New) A kit according to Claim 40, wherein the kit is bioresorbable.

43. (New) A kit according to Claim 40, wherein the kit is non-toxic.

Remarks

Applicant appreciates the thorough examination of the present application as evidenced by the Office Action mailed May 21, 2002. Claims 1-39 are pending in the present application. Applicant has added new Claims 40-43. Support for new Claims 40-43 can be found in the claims and in the present application at page 7, lines 5-11, among other places. Applicant has cancelled Claim 36 for the purpose of rewriting. Applicant has also cancelled Claim 38. Applicant has also taken this opportunity to amend the specification to correct a typographical error on page 1, line 28.

Claims 26-34 and 38 stand rejected under 35 U.S.C. § 112, second paragraph. Claim 38 is objected to under 37 C.F.R. § 1.75(c). Claims 1, 2, 4-10, 12, 13, 17, 18, 22, and 36 stand rejected under 35 U.S.C. § 103. Claims 1, 3, 11, 14-16, 21, 22, 36, 37, and 39 stand rejected under 35 U.S.C. § 103. Claims 1, 19, and 20 stand rejected under 35 U.S.C. § 103. Claims 23-35 stand rejected under 35 U.S.C. § 103.

Applicant addresses each of these objections or rejections below.

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I. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 26-34 and 38 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicant has amended Claim 23 to include a recitation that refers to "a composition," thus, providing antecedent basis for "said composition" and "the composition" recited in Claims 26-34. Amended Claim 23 also sets forth steps involved in the method of using the composition recited in the claims. Applicant has cancelled Claim 38. Applicant respectfully submits that these claim amendments are supported by the application as filed and respectfully request entry thereof.

Accordingly, Applicant respectfully requests that the rejection of Claims Claims 26-34 and 38 under 35 U.S.C. § 112, second paragraph, be withdrawn.

II. Claim Objections

Claim 38 is objected to under 37 C.F.R. § 1.75(c). As stated above, Applicant has cancelled Claim 38, and amended Claim 23 recites steps involved in the method of using the composition as recited in the present claims. Therefore, Applicant respectfully requests that this objection be withdrawn.

III. Claim Rejections Under 35 U.S.C. § 103

A. Claims 1, 2, 4-10, 12, 13, 17, 18, 22, and 36 are patentable under 35 U.S.C. § 103

Claims 1, 2, 4-10, 12, 13, 17, 18, 22, and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,258,175 to Davies (Davies). More specifically, at page 3, the Action states that "it would have been obvious to one of ordinary skill in this art at the time the invention was made having the Davies patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition." Applicant respectfully traverses this rejection.

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In order to establish a *prima facie* case of obviousness, three basic criteria must be met. *See* M.P.E.P. § 2143. First, the prior art reference or combination of references must teach or suggest all the claim limitations. *See In re Wilson*, 165 U.S.P.Q. 494 (C.C.P.A. 1970). Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings in order to arrive at the claimed invention. *See In re Oetiker,* 24 U.S.P.Q.2d 1443, 1446 (Fed. Cir. 1992); *In re Fine*, 837 F.2d at 1074; *In re Skinner*, 2 U.S.P.Q.2d 1788, 1790 (Bd. Pat. App. & Int. 1986). Third, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

In the present case, the Action has not established a *prima facie* case of obviousness. Davies proposes a dextrin derivative, in which a proportion of the hydroxyl groups in the dextrin derivative have been replaced by strongly acidic groups, wherein the dextrin derivative is useful in treatment of poisoning or drug overdose. *See* Abstract.

Applicant submits that Davies does not teach or suggest all the claim elements of the present invention. Unlike Davies, the present invention is directed toward a polysaccharide dextrin useful for preventing or reducing the incidence of adhesions in or associated with a body cavity as recited in Claim 1. Thus, the present invention is directed toward a dextrin derivative specifically formulated for use for a biologically distinct process.

Applicant further submits that Davies does not provide sufficient motivation to modify its teachings to arrive at the present invention. Where Davies proposes a dextrin derivative formulated for the treatment of poisoning or drug overdose, one skilled in the art would not be motivated to use the proposed dextrin derivative of Davies as a composition useful for preventing or reducing the incidence of adhesions in or associated with a body cavity as recited in Claim 1. Moreover, in view of the lack of teaching or suggestion, Applicants submit that Davies does not provide a reasonable expectation of success of arriving at the present invention. Accordingly, Davies does not

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teach or suggest all the claim elements of the present invention, does not provide sufficient motivation to modify its teachings to arrive at the present invention, and does not provide a reasonable expectation of success of arriving at the present invention. Thus, Davies does not render the present invention obvious under 35 U.S.C. § 103.

B. Claims 1, 3, 11, 14-16, 21, 22, 36, 37, and 39 are patentable under 35 U.S.C. § 103

Claims 1, 3, 11, 14-16, 21, 22, 36, 37, and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,587,175 to Viegas et al. (Viegas et al.). More specifically, the Action states at page 4, "it would have been obvious to one of ordinary skill in this art at the time the invention was made having the Viegas patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition." Applicant respectfully traverses this rejection.

Applicant respectfully submits that Viegas et al. does not teach or suggest all the claim elements of the present invention, does not provide sufficient motivation to modify its teachings to arrive at the present invention, and does not provide a reasonable expectation of success of arriving at the present invention, as required to establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

Viegas et al. proposes an aqueous pharmaceutical vehicle comprising representative film forming polymers that include, but are not limited to polydextrose, cyclodextrin, maltodextrin, dextran, and polydextrose. *See* Col. 6, lines 33-35. However, Viegas does not teach or suggest a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin in an amount effective to prevent or reduce such adhesions, wherein the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain

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a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other as recited in Claim 1. Viegas et al. also does not suggest modification of its teachings to arrive at the present invention. Thus, where Viegas et al. fails to teach or suggest all the claim elements of the present invention and fails to suggest modification of its teachings to arrive at the present invention, Viegas et al. does not render the present invention obvious under 35 U.S.C. § 103.

C. Claims 1, 19, and 20 are patentable under 35 U.S.C. §103

Claims 1, 19, and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,230,933 to Apfeld et al. (Apfeld et al.). More specifically, at page 5 the Action states, "it would have been obvious to one of ordinary skill in this art at the time the invention was made having the Apfeld patent before him to obtain the claimed composition in view of the closely related structure of the dextrin derivative and similar components present in the composition." Applicants respectfully traverse this rejection.

Apfeld et al. proposes "a novel acid resistant release coated food casing. The invention is particularly useful with acidic casings, particularly tubular nonfibrous casings adapted for processing foodstuffs such as sausages especially frankfurters." Col. 5, lines 33-37. Additionally, Apfeld et al. proposes the following:

> The peeling composition according to the present invention comprises a mixture of a water-soluble cellulose ether such as carboxymethylcellulose with a dextrin. Preferably such composition will also include lecithin and to facilitate formation of self-sustaining, deshirrable, shirred sticks of casing will also preferably contain an anti-pleat lock agent, such as an oil, and a surfactant. Other ingredients may also be utilized e.g. in shirring solutions. Typically employed casing additives are known to the art and may include, for example, humectants, antimycotics, lubricants and antioxidants.

Col. 4, lines 33-48. Thus, Apfeld et al. clearly does not teach or suggest a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing

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the polysaccharide dextrin in an amount effective to prevent or reduce such adhesions, wherein the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other as recited in Claim 1.

Moreover, Apfeld et al. does not provide sufficient motivation to arrive at the present invention. Applicant respectfully submits that one skilled in the art would not be motivated to use a composition of Apfeld et al. specifically formulated for food casing as a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin in an amount effective to prevent or reduce such adhesions as recited in Claim 1. Additionally, in view of the lack of guidance associated with Apfeld et al., Applicant submits that Apfeld et al. does not provide a reasonable expectation of success of arriving at the present invention as recited in Claim 1. Thus, Apfeld et al. does not render the present invention obvious under 35 U.S.C. § 103.

D. Claims 23-35 are patentable under 35 U.S.C. § 103

Claims 23-35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Viegas et al. in view of U.S. Patent No. 4,886,789 to Milner (Milner). More specifically, the Action reiterates the characterization of Viegas et al., and states at page 6, that "it would have been obvious to one skilled in the art at the time the invention was made to prevent adhesion of organs during the healing process as disclosed in the Viegas patent by applying the dextrin to the peritoneal cavity in view of the recognition in the art, as suggested in the Milner patent, that dextrin does not pass from the abdominal cavity through the peritoneal membrane and thus does not cause a rapid drop in the osmotic pressure." Applicants respectfully traverse this rejection.

Contrary to the assertions of the Action, Viegas et al., alone or in combination with Milner, does not teach or suggest the present invention and

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does not provide a reasonable expectation of success of arriving at the present invention. As stated above, Viegas et al. does not propose a composition comprising an aqueous formulation containing the polysaccharide dextrin in an amount effective to prevent or reduce such adhesions, wherein the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other as recited in Claim 1. Milner is directed to a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture, wherein the mixture includes at least 15% by weight of glucose polymers having a DP greater than 12. *See* Abstract. Thus, Milner also does not recite a composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin in an amount effective to prevent or reduce such adhesions as recited in Claim 1. Applicants submit that even if combined, these references do not teach or suggest the present invention directed to a composition comprising, *inter alia*, an aqueous formulation containing the polysaccharide dextrin as recited in Claim 1. Milner's proposal related to a peritoneal dialysis composition comprising a glucose polymer mixture does not supply the missing recitations necessary to arrive at the composition for preventing or reducing the incidence of adhesions in or associated with a body cavity comprising an aqueous formulation containing the polysaccharide dextrin in an amount effective to prevent or reduce such adhesions as recited in Claim 1. Accordingly, Applicant respectfully submits that Viegas et al., alone or in combination with Milner, does not render the present invention obvious under 35 U.S.C. § 103.

For at least the foregoing reasons, Applicant respectfully submits that the Action fails to establish a *prima facie* case of obviousness under 35 U.S.C. § 103, and requests that this rejection be withdrawn.

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IV. Conclusion

In view of the foregoing remarks, Applicant respectfully requests that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course. Any questions that the Examiner may have should be directed to the undersigned, who may be reached at (919) 854-1400.

Respectfully submitted,

Kenneth D. Sibley
Registration No. 31,665

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PATENT TRADEMARK OFFICE

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on August 20, 2002.

Vickie Diane Prior
Date of Signature: August 20, 2002

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Version With Markings To Show Changes Made

In the Specification:

Please replace the paragraph at page 1, line 21 through page 2, line 3 with the following replacement paragraph:

-- WO 92/21354 describes a surgical adhesion as the attachment of organs or tissues to each other through scar tissue. A formation of scar tissue is described as a normal sequel to surgery or other tissue injury and is required for proper wound healing. In some cases, however, the scar tissue overgrows the intended region and creates surgical adhesions. These scar tissue surgical adhesions restrict the normal mobility and function of affected body parts. The invention disclosed in WP 92/21354 is based on the discovery that anionic polymers effectively inhibit invasion of cells associated with detrimental healing processes, ie, fibrosis, and **[scaring]** scarring. In particular, certain inhibitory anionic polymers are useful to inhibit fibroblast invasion, thus regulating the healing process and preventing fibrosis. Anionic polymers specified in WO 92/21354 include dextran sulfate, pentosan polysulfate as well as natural proteoglycans, or the glycosaminoglycan moieties of proteoglycans, including dermatan sulfate, chondroitin sulfate, keratan sulfate, heparan sulfate, heparin and alginate. --

In the Claims:

Please amend the following claims:

22. (Amended) A composition according to Claim 1 which further comprises **[includes]** a compound selected from the group consisting of **[one or more of the following compounds,]** glycosolaminoglycan, an antibiotic agent, prostacyclin or an analogue thereof, a fibrinolytic agent or an analogue thereof, an anti-inflammatory agent or an analogue thereof, dextrin sulphate and**[/or]** methylene blue.

23. (Amended) A method of preventing or reducing the incidence of adhesions in or associated with a body cavity, comprising **[which comprises]**

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introducing into the body cavity a composition comprising an aqueous formulation further comprising a **[containing the]** polysaccharide dextrin in an amount effective to prevent or reduce the incidence of such adhesions, wherein the dextrin comprises **[contains]** more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other.